

**REMARKS**

In the Final Office Action dated July 25, 2008, the Examiner objected to claim based on informalities; rejected claims 1-23 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,620,356 to Wong et al. ("Wong"); and rejected claims 1-23 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent Application No. 2001/0021764 to Weisse et al. ("Weisse").

By this Amendment, Applicant has amended claims 1, 3, 5-8, and 16-18 and has canceled claims 13, 20, 21, and 23. Accordingly, claims 1-12, 14, 16-19, and 22 are currently pending in this application. No new matter has been added by this Amendment.

Independent claim 1 has been amended to recite, among other things, a "membrane having an open-nanoporous morphology producible by shaping a polymer blend, loading the polymer blend with a foaming gas at a superatmospheric pressure . . . said polymer blend being a homogeneous hydrophilic polymer blend having a hydrophilicity that allows spontaneous wetting of the membrane surface with blood, plasma, or other aqueous solutions, comprising components . . . and the glass transition temperature of the components of the polymer blend are not more different than 150°C." (Emphasis added.) Support for these claim amendments can be found in the specification, for example, at page 3, line 24 - page 4, line 19 and at page 11, lines 10-17.

Applicant respectfully traverses the rejection of claims 1-23 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious

over Wong. Wong does not disclose each and every limitation of amended independent claim 1, for example, and thus, cannot anticipate claim 1. Moreover, Applicant respectfully submits that the Examiner has failed to establish a prima facie case of obviousness because the Examiner has not properly determined the scope and content of the prior art and has not properly ascertained the differences between the prior art and the pending claims. Graham v. John Deere Co., 383 U.S. 1, 17, 148 U.S.P.Q. 459, 467 (1966). Moreover, the Examiner has not established that Wong teaches all the present claim limitations.

The Examiner contends that "all the claims are product by process." (Office Action at 2.) Regarding product-by-process claims, courts have held that "[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Moreover, "[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially . . . where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." In re Gamero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (emphasis added). The Examiner further contends, however, that "[t]he claims do not recite any additional distinguishable structure." (Office Action at 2.) Applicant strongly disagrees and submits that the Examiner has failed to appreciate the differences between the distinctive structural characteristics of the membrane of the claimed invention and those of the processes disclosed in Wong. In fact, in the Final Office Action, failed to even address the distinctive structural characteristics of the claimed product resulting from

the claimed process. Nevertheless, independent claim 1 has been amended to recite additional distinctive structural characteristics of the claimed product that further render claim 1 allowable over Wong.

The Examiner contends that "Wong teaches a porous membrane made from blends or block co-polymers of hydrophobic and hydrophilic components by the method of foaming using a foaming gas. See Wong abstract, column 3, line 30 0 column 5, line 12, the table in column 6, and working examples." Applicant disagrees and submits that the Examiner has misunderstood the teachings of Wong. Wong does not disclose preparing a membrane by a foaming process, as required by the claimed invention. *Instead*, Wong discloses membrane preparation by a phase separation process. The structure of a membrane prepared by a the claimed foaming process differs significantly from that of a membrane prepared by the phase separation process of Wong, as described below.

The phase separation process disclosed in Wong provides for a polymer to be dissolved in a solvent and the resulting polymer solution is transferred into a pressure cell. The polymer concentration in the solvent is about 10-25% by weight. The solution is then treated with a gas or a supercritical fluid (SCF), such as carbon dioxide, under pressure and temperature conditions. The gas or SCF is used as a non-solvent (replacing liquid non-solvents known in the prior art), to effect a phase separation of the mixed polymer solutions and thus creating an open porous polymer structure. The membranes prepared from the phase separation process disclosed in Wong result in a highly porous structure.

In contrast, the foaming gas used in the foaming process recited in amended claim 1, for example, serves to form a porous structure by the volume expansion of the foaming gas, which differs significantly from the use of a gas or SCF functioning as a non-solvent to achieve a phase separation of mixed polymer solutions as disclosed in Wong. As discussed above, the phase separation process in Wong begins with a polymer solution and separates or inverts the phases using a non-solvent, which results in a membrane having pores significantly larger than those provided by the process recited in the claimed invention. Conversely, the “foaming process,” recited in amended independent claim 1, does not require a solution of a polymer in a solvent. The present invention also does not require that a solvent be used in the process of foaming the inventive membrane. As discussed in the present application, a solution of the polymer is only used in connection with preparing thin film-shaped starting specimens for conducting the experimental examples described in the present application, and not for preparing the claimed membrane. In the foaming process to prepare the membrane recited in amended independent claim 1, the polymer blend is directly contacted with a foaming gas, which is loaded into and dissolved in the pure solvent-free polymer blend material. The foaming gas then expands to form the open-nanoporous structure, as recited in amended independent claim 1. The membrane formed by this process is a less porous structure due in part to the pressure release and an increase in temperature upon expansion of the foaming gas, when compared to membranes prepared by phase separation as disclosed in Wong.

As described above, membranes created by the phase separation process disclosed in Wong are known by those of skill in the art to have low density and high

porosity, while membranes created by the process recited in amended independent claim 1 have much higher densities and much lower porosities. These structural differences are significant. Thus, Wong does not disclose or suggest the product made by the process recited in amended independent claim 1.

In addition, Applicant submits that Wong does not disclose an "open nanoporous morphology" having the characteristics of the membrane recited in amended independent claim 1, wherein the polymer blend, which is loaded with the foaming gas, is a "homogeneous hydrophilic polymer blend having a hydrophilicity that allows spontaneous wetting of the membrane surface with blood, plasma, or other aqueous solutions." Wong does not disclose a membrane prepared having such a spontaneously wettable surface. This hydrophilicity and wettability of the claimed membrane eliminates the need for a hydrophilic coating, as required by prior art membranes, which can readily wear off. Rather, this characteristic of the claimed membrane is an integral property to the membrane surface, which results from the polymer blend utilized and the process with which the claimed membrane is made. Moreover, Wong does not disclose a polymer blend for preparing a membrane having hydrophilic and hydrophobic components, wherein "the glass transition temperature of the components of the polymer blend are not more different than 150°C." Both of these features are essential to the preparation of the open-nanoporous membrane recited in amended independent claim 1, and provide the claimed open-nanoporous membrane with characteristics that are not present in the membrane achieved by the phase separation process disclosed in Wong.

Accordingly, for at least all of the reasons discussed above, and upon considering the structural characteristics imparted by the process steps of amended independent claim 1, it is evident that Wong does not anticipate this claim. Nor would one of skill in the art having knowledge of Wong at the time of the invention achieve the invention recited in amended independent claim 1. Therefore, amended independent claim 1 is allowable over Wong. Accordingly, claims 2-12, 16-19, and 22 are allowable at least due to their dependence from allowable independent claim 1 and due to their additional recitations of novel subject matter.

In addition, Applicant objects to the fact that the Examiner failed to sufficiently, and in detailed fashion, address the additional recitations of novel subject matter disclosed in the dependent claims of this application in the rejections based on Wong. Applicant respectfully asks that each dependent claim be addressed in any Office Action in response to this Amendment. Moreover, Applicant kindly asks that, in any subsequent Office Action, the Examiner provide detailed citations (i.e., column and line numbers) from the Wong to show where alleged support for the Examiner's arguments can be found.

Applicant respectfully traverses the rejection of claims 1-23 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Weisse. Weisse does not disclose or suggest each and every limitation of amended independent claim 1, for example, and thus, cannot anticipate claim 1. The Examiner contends that Weisse "teaches a porous membrane made from block co-polymer of sulfonated polysulfone for applications such as dialysis." (Office Action at 3.) Weisse does not, however, disclose or suggest a "membrane having an open-

nanoporous morphology producible by shaping a polymer blend," as recited in amended independent claim 1, nor does Weisse disclose or suggest a membrane prepared by loading a foaming gas into a polymer blend having hydrophilic and hydrophobic components, as recited in amended independent claim 1, wherein the process of making the membrane is integral to the structural makeup of the membrane. Nor does Weisse disclose a spontaneously wettable membrane, as recited in amended independent claim 1.

Applicant further submits that the Examiner's rejection based on Weisse is severely deficient. The Examiner concedes that Weisse "teaches a porous membrane made from block co-polymer of sulfonated polysulfone for applications such as dialysis." (Office Action at 4.) The Examiner contends, however, that the reference also teaches having blends of polysulfone polymers with PVP as known in the art in the background information -- see paragraph 0016. Thus the claims are anticipated, or at least would be obvious to one of ordinary skill in the art at the time of invention that blends can be used to make a hydrophobic polymer hydrophilic instead of the block copolymer as taught by the reference." (Id.) Applicant disagrees and argues that the Examiner has grossly over-stated the teachings of Weisse and has also grossly over-simplified the invention as recited in amended independent claim 1, for example. The Examiner has neglected to properly consider the structure imparted by the process steps for making the claimed membrane. As discussed above with respect to Wong, the process steps recited in amended independent claim 1 impart distinctive structural characteristics to the manufactured membrane. Accordingly, the Examiner is required to consider these characteristics, which are described above. Upon considering the structural

characteristics imparted by the process steps of amended independent claim 1, it is clear that Weisse does not anticipate this claim, nor would one of skill in the art having knowledge of Weisse at the time of the invention achieve the invention recited in amended independent claim 1.

Thus, for at least these reasons, amended independent claim 1 is allowable over Weisse. Accordingly, claims 2-12, 16-19, and 22 are allowable at least due to their dependence from allowable independent claim 1 and due to their additional recitations of novel subject matter.

In addition, Applicant objects to the fact that the Examiner failed to sufficiently, and in detailed fashion, address the additional recitations of novel subject matter disclosed in the dependent claims of this application in the rejections based on Weisse. Applicant respectfully asks that each dependent claim be addressed in any Office Action in response to this Amendment. Moreover, Applicant kindly asks that, in any subsequent Office Action, the Examiner provide detailed citations (i.e., column and line numbers) from the Weisse to show where alleged support for the Examiner's arguments can be found.

#### **CONCLUSION**

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.



Should the Examiner perceive that this application is not now in condition for allowance, Applicant asks that he call the undersigned at (202) 408-4387.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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